



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
**11.11.1998 Bulletin 1998/46**

(51) Int Cl.<sup>6</sup>: **A61F 2/06**

(21) Application number: **98303534.6**

(22) Date of filing: **06.05.1998**

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU**  
**MC NL PT SE**  
 Designated Extension States:  
**AL LT LV MK RO SI**

(72) Inventor: **Loeffler, Joseph P.**  
**Mountain View, California 94041 (US)**

(74) Representative:  
**McLeish, Nicholas Alistair Maxwell et al**  
**Boult Wade Tennant**  
**27 Fumival Street**  
**London EC4A 1PQ (GB)**

(30) Priority: **06.05.1997 US 851111**

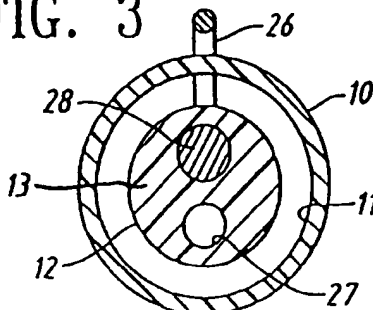
(71) Applicant: **Advanced Cardiovascular Systems,**  
**Inc.**  
**Santa Clara, California 95054 (US)**

(54) **Passive perfusion stent delivery system**

(57) A stent delivery method and system are disclosed. The system generally includes an elongated delivery sheath (10) and a perfusion catheter (12) disposed within a sheath lumen (11) of the sheath having an expandable member (14) on its distal extremity. The sheath includes perfusion ports (1,2) to maintain blood flow to perfusion ports in the catheter during delivery of

the stent. A manipulating device (15, 33, 34) is provided at the proximal end of the delivery system to effect relative axial movement between the sheath and the catheter so as to expose the stent (16) mounted on the expandable member (14) on the catheter within a body lumen such as a coronary artery and to allow the expansion of the stent by the expansion of the expandable member.

**FIG. 3**



**Description**

This invention generally relates to devices for the treatment of heart disease and, more particularly, to endoarterial prostheses, which commonly are called stents.

Several interventional treatment modalities presently are used for heart disease, including balloon and laser angioplasty, atherectomy, and by-pass surgery. In typical balloon angioplasty procedures, a guiding catheter having a pre-formed distal tip percutaneously is introduced through the femoral artery into the cardiovascular system of a patient in a conventional Seldinger technique, and is advanced within the cardiovascular system until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. A guide wire is positioned within an inner lumen of a dilatation catheter and then the catheter is advanced over the guide wire, through the guiding catheter to the distal end of the guiding catheter. The guide wire first is advanced out of the distal end of the guiding catheter into the coronary vasculature of the patient until the distal end of the guide wire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon on the distal portion thereof is advanced into the coronary anatomy over the previously introduced guide wire until the balloon of the dilatation catheter properly is positioned across the lesion.

Once in position across the lesion, the balloon, which is made of relatively inelastic materials, is inflated to a predetermined size with radiopaque liquid at relatively high pressure (e.g., greater than 4.052 bars (4 atmospheres)) to compress the arteriosclerotic plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon then is deflated so that blood flow can be resumed through the dilated artery and the dilatation catheter can be removed therefrom.

Further details of dilatation catheters, guide wires, and devices associated therewith for angioplasty procedures can be found in U.S. Patent 4,323,071 (Simpson-Robert); U.S. Patent 4,439,185 (Lindquist); U.S. Patent 4,516,972 (Samson); U.S. Patent 4,538,622 (Samson, et al.); U.S. Patent 4,554,929 (Samson, et al.); U.S. Patent 4,616,652 (Simpson); U.S. Patent 4,638,805 (Powell); and U.S. Patent 4,748,982 (Horzewski, et al.).

A problem which can occur during balloon angioplasty procedures is the formation of intimal flaps, which can collapse and occlude the artery when the balloon is deflated at the end of the angioplasty procedure. In the event of a partial or total occlusion of a coronary artery by the collapse of a dissected arterial lining after the balloon is deflated, the patient is put in an extremely dangerous situation requiring immediate medical attention, particularly in the coronary arteries. Another problem characteristic of balloon angioplasty procedures is the large number of patients who are subject to restenosis in the treated artery. In the case of restenosis, a previously treated artery may once again be subjected to balloon angioplasty or even to less conservative treatment such as by-pass surgery.

A significant focus of recent development work in the treatment of heart disease has been directed to endoprosthetic devices called stents. Stents are generally cylindrically-shaped intravascular devices which are placed within a damaged artery to hold it open. A stent can be used to prevent restenosis and to maintain the patency of blood vessel immediately after other intravascular treatments. In some circumstances, stents also can be used as the primary treatment device when expanded to dilate a stenosis and then left in place.

But the rapid and effective delivery of a stent to the desired location within the vasculature has been found to be difficult, particularly in those situations in which an intimal flap has occluded an artery. Attempts to advance a stent into regions of coronary arteries occluded by dissected arterial linings have not been very successful.

Two basic methods and systems have been developed for delivering stents to desired locations within body lumens. One method and system involves compressing or otherwise reducing the diameter of an expandable stent, disposing the compressed stent within a lumen provided in the distal end of a tubular catheter, advancing the catheter through the vasculature of the patient until the distal end of the catheter is immediately adjacent to the desired vascular location and then pushing the stent out of the distal end of the catheter into the desired location. Once out of the catheter, the compressed stent expands or is expanded to thereby hold open the artery or other body lumen into which it is placed.

Another method and system involves disposing a compressed or otherwise small diameter stent about an expandable member, such as a balloon, on the distal end of a catheter, advancing the catheter through the vascular system of a patient until the stent is in the desired location within a blood vessel, and then expanding the expandable member on the catheter to expand the stent within the blood vessel. The expanded expandable member then is contracted or deflated and the catheter withdrawn, leaving the expanded stent within the blood vessel, holding open the passageway thereof.

The following references illustrate various types of stents and stent delivery systems. The list is meant to be exemplary, not exhaustive on the subject.

U.S. 3,868,956	U.S. 4,503,569	U.S. 4,512,338
U.S. 4,553,545	U.S. 4,560,374	U.S. 4,655,771
U.S. 4,665,918	U.S. 4,733,665	U.S. 4,760,849
U.S. 4,762,128	U.S. 4,768,507	U.S. 4,795,458

(continued)

U.S. 4,800,882	U.S. 4,830,003	U.S. 4,856,516
U.S. 4,878,906	U.S. 4,886,062	U.S. 4,907,336
U.S. 4,913,141	U.S. 4,923,464	U.S. 4,950,227
U.S. 5,458,615		

What has been needed and heretofore unavailable is a stent delivery system which can be used quickly and easily in a wide variety of situations and particularly in emergency situations, when a dissected arterial lining has collapsed and has occluded the flow of blood to a vital organ. The present invention satisfies this need.

In addition, because the expandable member such as a balloon is inflated, the flow of blood in the artery or vessel being treated is occluded. The balloon only can be inflated for a limited amount of time, typically on the order of 15 to 60 seconds. A longer inflation time would be desirable because it would allow more time for the surgeon to deploy the stent, allow maximum stent-to-vessel conformity, and permit good seating in the artery of the stent. On the other hand, risks of prolonged balloon inflation time include angina or ischemic conditions in the tissue distal to the catheter.

The importance of continuous blood flow during percutaneous transluminal coronary angioplasty or during procedures performed in the peripheral vascular is well recognized. Indeed, a perfusion-type dilatation catheter for angioplasty has been introduced into the marketplace by Advanced Cardiovascular Systems, Inc. This catheter, which can take the form of an over-the-wire, a fixed wire, or a rapid-exchange type catheter, has one or more perfusion ports proximal to and one or more perfusion ports distal to, the dilatation balloon. The perfusion ports are in fluid communication with a guide wire- receiving inner lumen which extends to the distal end of the catheter. When the balloon is inflated to dilate a stenosis, oxygenated blood in the artery or aorta, or both, is forced through the proximal perfusion ports, through the inner lumen of the catheter, and out of the distal perfusion ports.

The rapid-exchange version of the perfusion-type dilatation catheter has a short, guide wire-receiving sleeve or inner lumen which extends through a distal portion of the catheter. The structure of the catheter allows for the rapid exchange of the catheter without the need for an exchange wire and without adding a guide wire extension to the proximal end of the guide wire. Details of such a rapid-exchange perfusion catheter are disclosed in, for example, U. S. Patent No. 5,040,548 (Yock).

Also of interest is U.S. Patent 5,368,566 (Crocker), which discloses a delivery and temporary stent catheter having a reinforced perfusion lumen. The temporary stent in the Crocker reference is used only for maintaining patency of a body lumen while permitting perfusion of fluid through the lumen. U.S. Patent No. 5,368,566 is not directed to the delivery of stents after angioplasty procedures.

U.S. Patent 5,222,971 (Willard et al.) discloses a temporary stent for supporting a region of a vessel comprising a stent portion and an actuator portion. The stent portion has an elongate perfusable vessel-supporting portion, wherein the stent provides a path radially, as well axially or longitudinally, for fluid flow.

There is, however, still a need for a stent delivery system that includes a mechanism for perfusing blood during delivery of the stent to the deployment site.

The present invention is directed to an improved stent delivery system which can position a stent quickly and easily into an occluded region of a blood vessel. In a preferred embodiment, the present invention stent delivery system includes a means for perfusing fluid.

One preferred embodiment of the present invention is directed to a catheter assembly for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of an expandable stent within the body lumen, wherein the assembly comprises an elongated delivery sheath having proximal and distal ends, a sheath lumen extending therein, a first port in the distal end being in fluid communication with the sheath lumen, and at least one sheath perfusion port at the proximal end in fluid communication with the sheath lumen.

Embodiments of the present invention also include an elongated catheter slidably disposed within the sheath lumen of the sheath, an expandable member proximally adjacent to the distal end of the catheter which receives on the exterior thereof the expandable stent, an inner lumen extending the length of said elongated catheter for receiving a guiding member therein and which extends the entire length of the inner lumen, and at least one catheter perfusion port in the catheter in fluid communication with the inner lumen. Further included are means for adjusting the relative axial positions of the catheter and the sheath to expose the expandable member so that expansion thereof expands the expandable stent.

Preferably, both the delivery sheath and the catheter have slits in the walls thereof which extend distally from their proximal ports to facilitate the rapid removal of these devices from the guide wire upon the withdrawal of the delivery system from the vascular system of the patient after the delivery of a stent. The distal end of the delivery sheath also may have slits in the walls thereof which extend a short distance proximally from its distal end, to facilitate in the relative axial position adjustment of the delivery sheath and catheter.

In a typical situation, the guide wire used to deliver a dilatation catheter through the vascular system to a stenotic region therein is left within the patient after the dilatation catheter has been removed therefrom. To maintain access to the stenotic region, the distal end of the guide wire should be positioned so that it crosses the stenotic region where the stent is to be placed.

The proximal end of the guide wire, which extends out of the patient, first is inserted through an elastic cone by threading the guide wire into the smaller aperture of the cone and out of the larger of the two apertures of the cone. Then the guide wire is inserted through the port in the distal end of the intravascular catheter, which has a stent mounted on the expandable member. The intravascular catheter is disposed within the delivery sheath with the distal end of the catheter extending out of the port in the distal end of the delivery sheath to facilitate the insertion of the proximal end of the guide wire.

The relative axial position between the delivery sheath and intravascular catheter is adjusted so that the expandable member on the distal extremity of the intravascular catheter with the expandable stent mounted thereon is pulled back into the inner lumen of the delivery sheath. The distal end of the delivery sheath then is tucked within the large aperture of the elastic cone. Tucking the delivery sheath within the elastic cone aids the advancement of the stent delivery system through the vascular system by providing the system with a profile suited for making turns through tortuous vessels. The delivery sheath and the catheter therein then are advanced through the vascular system, preferably over a guide wire which extends from outside the patient to the desired coronary artery, until the stent mounted on the expandable member of the intravascular catheter is positioned within the stenotic region of the target vessel.

The relative axial positions of the delivery sheath and the intravascular catheter having the stent thereon are adjusted so that the sheath is withdrawn proximally (in a direction away from the patient) to expose the distal end of the vascular catheter and the expandable stent. As the relative axial positions are adjusted, the cone disengages from the sheath and collapses upon the distal end of the catheter. Once the stent is completely out of the delivery sheath, the expandable member on the intravascular catheter can be expanded to expand the stent against the walls of the blood vessel. After expanding the stent, the expandable member on the vascular catheter is contracted so that the catheter can be removed from the patient, leaving the expanded stent in its desired position in the target vessel.

During delivery of the stent to the deployment site, the perfusion ports within the sheath and the catheter provide continuous blood flow via the sheath lumen of the sheath and the inner lumen of the catheter. From the inner lumen, the effluent blood passes through the perfusion ports at the distal end of the catheter to the tissue distal to the catheter. Even as the sheath is withdrawn, the perfusion ports in the sheath enable continuous flow of blood to the perfusion ports in the catheter shaft.

Beneficially, the present invention perfusion ports in the sheath and catheter prevent or minimize ischemic conditions from developing in the patient. Moreover, the perfusion of blood distal to the inflated balloon allows for long term dilatations.

The delivery sheath and the catheter may be withdrawn together or the sheath may be withdrawn first, followed by withdrawal of the catheter. The sheath and the catheter can be peeled away from the guide wire, with the guide wire sliding through the slits which extend distally from the proximal ports of the catheter. The exposed section of the guide wire is secured, e.g., manually held in place, so that the sheath and the intravascular catheter can be pulled off the proximal end of the guide wire.

In one exemplary embodiment of the invention, an over-the-wire catheter system is used to deliver a stent to a location in the vascular system. The over-the-wire catheter includes a proximal shaft and a distal shaft which are retractable in the proximal direction by operation of a sheath retraction switch on a delivery handle. An elongated sheath is at the distal end of the distal shaft and covers and protects the stent and balloon member on the catheter shaft during intravascular delivery. When the sheath retraction switch is moved in the proximal direction, the sheath is caused to move proximally, thereby exposing the stent so that it may be deployed.

The delivery system of the invention effectively can deliver a stent to a desired location within a vessel of a patient, can allow the stent to be secured within the desired location, and can be removed quickly and easily. These and other advantages of the present invention will become more apparent from the following detailed description when taken in conjunction with the accompanying exemplary drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a partial longitudinal cross-sectional view of a stent delivery system which embodies features of the invention including perfusion ports in the catheter and sheath.

FIG. 2 is a top view of the delivery sheath with perfusion ports and elastic cone of the stent delivery system shown in FIG. 1.

FIG. 3 is a transverse cross-sectional view taken along the lines 3-3 shown in FIG. 1.

FIG. 4 is a transverse cross-sectional view taken along the lines 4-4 shown in FIG. 1.

FIG. 5 illustrates a stent mounted on the outer surface of a balloon of an exemplary embodiment intravascular

catheter such as the one shown in FIG. 1.

FIG. 6 illustrates the advancement of the stent delivery system such as shown in FIG. 5 into an artery which has been damaged by an intravascular procedure, such as an angioplasty procedure, and the location of the elastic cone, prior to the relative axial position adjustment of the delivery sheath and intravascular catheter.

FIG. 7 illustrates the inflation of the balloon on the intravascular catheter shown in FIG. 1, which expands the stent mounted on the exterior thereof, and the location of the elastic cone after the relative axial position adjustment of the delivery sheath and intravascular catheter.

FIG. 8 illustrates the expanded stent disposed within a damaged arterial section maintaining the patency thereof.

FIG. 9 is a partial cross-sectional view of the manipulator shown in FIG. 1.

FIG. 10 is a perspective view of an alternative manipulator mounted on the proximal end of the delivery system shown in FIG. 1.

FIG. 11 is a plan view of the manipulator shown in FIG. 10.

FIG. 12 is an elevational view, partially in section, of the manipulator shown in FIG. 10.

FIG. 13 is a longitudinal view of a stent delivery system which embodies features of an over-the-wire catheter system.

FIG. 14 is a partial plan view of the delivery sheath of the stent delivery system depicted in FIG. 13 including optional perfusion ports in the sheath.

FIG. 15 is a longitudinal view of a stent delivery system wherein the delivery sheath is depicted in its withdrawn position.

FIG. 16 is a partial plan view of the stent delivery system of FIG. 15 depicting the delivery sheath after it has been withdrawn from the delivery stent.

FIG. 17 is a cross-sectional view of the distal portion of the delivery sheath of the stent delivery system of FIG. 15, with perfusion ports, illustrating the sheath as it is partially withdrawn from the stent.

FIG. 18 is a cross-sectional view taken along line 18-18 of FIG. 17, depicting the distal end of the catheter and the elastic cone.

FIG. 19 is a cross-sectional view taken along line 19-19 of FIG. 17, depicting the sheath in relation to the catheter system.

FIGS. 1-4 illustrate preferred embodiments of a stent delivery system having features of the invention. Generally, the delivery system includes a delivery sheath 10 which has a sheath lumen 11 and a catheter 12 disposed within the sheath lumen 11. As shown in FIG. 1, the delivery sheath 10 preferably includes proximal sheath perfusion ports 1 and distal sheath perfusion ports 2. The perfusion ports 1, 2 are in fluid communication with the sheath lumen 11. The positioning of the ports 1, 2 along the sheath 10, of course, may be varied depending upon application. Also, the size, shape, and orientation of the perfusion ports 1, 2 can be changed as needed. For example, the perfusion ports in alternative embodiments may be round holes, vertical slots, horizontal slits, and the like.

The exemplary embodiment intravascular catheter 12 shown in FIG. 1 has an elongated catheter body 13 and a balloon 14 on the distal portion of the catheter body 13. A manipulating device 15 is provided on the distal end of the delivery system which is employed to effect relative axial or longitudinal movement between the delivery sheath 10 and the intravascular catheter 12. An expandable stent 16, which is to be delivered within a body lumen of a patient, is mounted on the exterior of the balloon 14. During the advancement of the stent delivery system through the vascular system to the region of an occlusion, the sheath 10 is tucked within an elastic cone 58. Figure 1 shows the location of the elastic cone 58 after the relative axial positions of the sheath 10 and catheter 12 are adjusted to expose the expandable stent 16.

The delivery sheath 10 has a distal port 17 in its distal end which is in fluid communication with the sheath lumen 11 and a proximal port 18 disposed proximally to the distal port. The distal portion of the delivery sheath 10 tapers down in a spherical-like manner so that the cross-sectional area is somewhat less in the distal region than is the cross-sectional area of the rest of the delivery sheath. A slit 19 extends from the proximal port 18 to a location just proximal to the distal port 17. In one embodiment, a plurality of slits 59 in the wall of the delivery sheath 10 extend a short distance from the distal port 17. As contemplated, the slits 59 would facilitate the relative axial position adjustment of the delivery sheath 10 and the intravascular catheter 12.

The intravascular catheter 12 has a distal port 20 and a proximal port 21 which are in fluid communication with a first inner lumen 22, which extends within the distal portion of the catheter 12 and is adapted to slidably receive a guide wire therein. A slit 23 extends from the catheter proximal port 21 to a location 24 proximal to the proximal end of the balloon 14. The proximal end of the guide wire-receiving first inner lumen 22 is provided with a ramp 25 to guide the proximal end of guide wire 26 out of the proximal port 21 of the intravascular catheter 12 when the catheter is mounted onto the guide wire, as will be discussed hereinafter. A second, much longer, inner lumen 27 is provided within the catheter body 13 to direct inflation fluid from the proximal end of the catheter body to the interior of the balloon 14.

At least one optional catheter perfusion port 3 is located at a proximal portion of the catheter body 13, and is in fluid communication with the first inner lumen 22. Thus, blood flows through the sheath perfusion ports 1, 2, then

through the sheath lumen 11, and ultimately through the catheter perfusion port 3 into the first inner lumen 22. The blood passes through the catheter distal port 20 or through optional perfusion ports at the distal end of the catheter body 13 to supply the tissue distal of the balloon 14.

Proximal to the proximal port 21 in the catheter body 13 is a stiffening member 28 which is disposed in third inner lumen 29 provided within the catheter body 13. As shown in the drawings, the third inner lumen 29 and the first inner lumen 22 may be the same lumen with a plug 30 separating the two lumens. The ramp 25 is on the distal side of the plug 30.

As illustrated in FIGS. 1 and 9, the manipulator 15 on the proximal end of the delivery system has a housing 31 with an interior chamber 32, a cap 33 rotatably mounted onto the distal end of the housing 31, an elongated drive member 34 which has male threads on the exterior thereof and which is at least partially disposed within the interior chamber 32, and a Luer lock 35 which is fixed within the proximal end of the housing 31. The proximal end 36 of the delivery sheath 10 is secured to the distal end 37 of the elongated drive member 34 which extends out of the distal end of the housing 31. As shown in more detail in FIG. 9, the proximal end 38 of the catheter body 13 passes through a passageway 39 in the elongated drive member 34 and is fixed within the Luer lock 35 by a suitable means such as an adhesive. The cap 33, which is rotatably mounted onto the distal end of the housing 31, is provided with an inner threaded collar 40 adapted to threadably engage the threaded exterior of the elongated drive member 34. Rotation of the cap 33 moves the drive member 34 axially to thereby effect relative axial movement between the delivery sheath 10 and the intravascular catheter 12. As can be seen from FIGS. 1 and 6, the sheath lumen 11 is axially spaced from the catheter 12, at catheter second inner lumen 27, in a substantially non-abutting manner. Thus, when the delivery sheath 10 overlies the intravascular catheter 12, there is little or no contact present at the interface between the sheath lumen 27 proximal to the distal end of the intravascular catheter 12.

In a typical situation, the stent delivery system of the present invention is used after an intravascular procedure has damaged the arterial lining of a patient to such an extent that the lining needs support to prevent it from collapsing into the arterial passageway thus compromising the sufficiency of the blood flow through the affected vessel. In these situations, there usually is a guide wire 26 (or other guiding member) in place which extends across the damaged section of the artery, such as is shown in FIG. 6. The proximal end of the guide wire 26, which extends out of the patient during the entire procedure, is inserted through the elastic cone 58 by threading the guide wire 26 into the small aperture 61 and out of the large aperture 60 of the cone 58. The guide wire 26 then is inserted through the distal port 20 in the distal end of the catheter 12 and is advanced proximally through the first inner lumen 22, until the proximal end of the guide wire impacts the ramp 25 and thereby is directed through the proximal port 21.

The catheter 12 preferably is positioned within the sheath lumen 11 of the delivery sheath 10 so that at least a significant portion of the proximal port 18 in the delivery sheath is in alignment with the proximal port 21 of the intravascular catheter. In this manner, proximal advancement of the guide wire 26 through the first inner lumen 22 of the catheter also will direct the proximal end of the guide wire out of the proximal port 18 in the delivery sheath 10. The delivery sheath 10 then is tucked within the elastic cone 58 by inserting the distal end of the delivery sheath 10 into the proximal end and large aperture 60 of the cone 58. The proximal end of the guide wire 26 then may be manually held to maintain the position of the guide wire within the vasculature of the patient, while the stent delivery system is advanced over the guide wire and through the vascular system.

A function of the elastic cone 58 is to facilitate the advancement of the stent delivery system. By tucking the distal end of delivery sheath 10 within the cone 58 as shown in FIG. 6, the stent delivery system has a profile suited for successfully maneuvering through the sharp turns and angles of the vasculature of the patient.

The advancement of the stent delivery system continues until the distal end of the catheter and the distal end of the sheath extend adjacent to, or across, the damaged arterial site. Next, the manipulator 15 on the proximal end of the delivery system is actuated by rotating the cap 33 on the proximal end of the housing 31 to move the delivery sheath 10 proximally with respect to the catheter 12 and to thereby expose the stent 16 mounted on the balloon 14. The elastic cone 58 disengages the delivery sheath 10 and collapses in engagement about the distal portion of the catheter 12, as is shown in FIG. 1.

When the balloon and the stent mounted thereon properly are placed within the damaged artery, inflation fluid is directed under substantial pressure through the manipulator Luer lock 35 and the catheter inflation lumen 27 in the catheter body 13 to the interior of the balloon 14, expanding the balloon and simultaneously expanding the stent 16 against the wall of the vessel in the target site as shown in FIG. 7. The delivery system (both the delivery sheath 10 and the catheter 12), then may be removed from the patient along with the guide wire 26, leaving the expanded stent 16 within the damaged arterial section to maintain the patency thereof, as is shown in FIG. 8.

The housing 31 of the manipulator 15 can be held in the palm of the physician's hand, the thumb and index finger being used to rotate the cap 33 and thereby to cause the necessary relative motion between the delivery sheath 10 and the intravascular catheter 12 to expose the stent 16 mounted on the balloon 14. The physician can operate an inflation device, such as that which is described in U.S. Patent 4,439,185, with his or her free hand, to inject inflation fluid through the Luer lock 35 into the interior of the balloon 14 to inflate the balloon and thereby to expand the stent

16 while holding the delivery system in place with the other hand. Upon deflating the balloon 14, the manipulator 15 can be actuated again by rotating the cap 33 with the fingers of the hand holding the manipulator 15, to cause relative rotation between the intravascular catheter 12 and the delivery sheath 10, to pull the intravascular catheter 12 back into the distal end of the delivery sheath 10 (or pushing the distal end of the sheath over the distal end of the intravascular catheter 12, depending upon the perspective). The entire assembly, including the guide wire 26, then can be removed from the patient.

The alternative manipulator 50 illustrated in FIGS. 10-12 generally includes a housing 51 with an interior chamber 52 and a slidable element 53 with a depending portion 54 which extends through a slot 55 in the wall of the housing and which is secured to the proximal end of the delivery sheath 10, which extends through an opening provided in the distal end of the housing. The catheter 12 extends out the proximal end of the delivery sheath 10, out of an opening in the proximal end of the housing 51, and into a Luer lock 56 secured to the proximal end of the housing. The proximal end of the catheter 12 is secured within the Luer lock 56 to be in fluid communication with the second inner inflation lumen 27 of the catheter, so that inflation fluid can be injected through the Luer lock to the interior of the balloon 14 on the catheter to expand the balloon and the stent 16 mounted thereon. As is evident from FIG. 10, moving element 53 on the exterior of the housing 51 will effect the relative axial movement between the delivery sheath 10 and the catheter 12, which relative axial movement is required to expose the expandable stent 16 mounted on the balloon 14. The slot 55 has narrowed portions near both ends thereof. These narrowed portions have widths that are just slightly smaller than the depending portion 54, so that the position of the slidable element 53 can be locked. The underside of the housing 51 may be provided with an undulated surface 57, which is adapted to receive the fingers of an operator to facilitate the gripping thereof.

In another exemplary embodiment of the invention, as depicted in FIGS. 13-19, an over-the-wire catheter system is employed to carry the delivery sheath and the stent within the vasculature of a patient to the damaged area. A guide wire 26 is used to cross the damaged area and to locate the position of interest within the patient, so that the intravascular catheter 12 can reach the area.

As is typical in over-the-wire catheter systems, the intravascular catheter 12 has an outer member 77 and an inner member 78 which are aligned coaxially. The inner member 78 has an inner lumen 79 which carries a guide wire 26. The guide wire can move freely within the inner lumen 79 in an axial direction.

In keeping with the invention, as depicted in FIGS. 13-19, the delivery sheath 10 is located at the distal end of a distal retractable sheath 74. The catheter 12 is slidably disposed within the delivery sheath 10 in the sheath inner lumen 11. The port 17 at the distal end of the delivery sheath 10 provides an opening through which the catheter 12 can extend.

The delivery sheath 10 has a flared portion or an expanded portion located at the distal end of the distal retractable sheath 74. It is contemplated that the delivery sheath 10 can be formed from the same shaft as the distal retractable sheath 74, or can be a separate member (not shown) attached to the distal end of the distal retractable sheath 74. The flared or enlarged diameter portion of the delivery sheath 10 must be large enough to accommodate the underlying balloon 14 and the expandable stent 16. It also is contemplated that the delivery sheath 10 might not have a flared portion as depicted, in order to reduce the profile of the delivery sheath 10.

A notch 80 at the distal end of the delivery sheath 10 is incorporated in order to provide a softer and more flexible distal end to the delivery sheath 10. When the intravascular catheter 12 is being urged through the vasculature of the patient, a softer distal end for the delivery sheath 10 is desirable, and the notch 80 provides flexibility and the required softness. More than one notch is contemplated to further increase flexibility and softness in the distal end of the delivery sheath 10. If a stiffer, less flexible end is desired, the delivery sheath 10 can be provided without any notch.

The distal retractable sheath 74 is connected to a proximal retractable sheath 75 comprises a member with a somewhat larger diameter and greater stiffness, than the distal retractable sheath 74. Thus, the distal end of the sheath will have more flexibility than the proximal end. It also is contemplated that the invention incorporate a retractable sheath characterized by only one diameter along its length, to provide uniform stiffness throughout.

An elastic cone 58 is attached to the intravascular catheter 12 near its distal tip. The elastic cone 58 has a large aperture 60 which is elastic enough to overlay the very distal end of the delivery sheath 10. The elastic cone also has a small aperture 61 at its distal end which is attached to the outer member 77 of the over-the-wire catheter by known methods such as heat shrinking or by an adhesive. The elastic cone 58 is intended to provide a covering over the distal end of the sheath 10, as the sheath moves through the tortuous vasculature, and will prevent the sheath 10 from getting caught up in the vasculature.

Further, the intravascular catheter 12 includes optional catheter perfusion ports 5 at a distal end thereof. The catheter perfusion ports 5 are in fluid communication with the inner lumen 79 of the inner member 78 of the over-the-wire catheter that carries the guide wire 26. An influx of blood optionally may be supplied to the distal perfusion ports 5 through the inner lumen 79, from a blood supply source 6, as is known in the art of perfusion catheters.

In addition, the preferred embodiment delivery sheath 10 includes sheath perfusion ports 4, as horizontal slots, illustrated in FIGS. 14 and 16. Of course, the size, shape, location, and orientation of the sheath perfusion ports 4 may be adjusted to accommodate particular applications. The perfusion ports 4 enable blood flow through the delivery

sheath 10. The sheath perfusion ports 4 are useful in one alternative embodiment of the catheter having proximal perfusion ports (not shown). Specifically, as the sheath 10 is retracted, the sheath perfusion ports 4 ensure continuous blood flow in the event the proximal catheter perfusion ports are covered or blocked by the delivery sheath 10 as it is retracted.

5 A blood supply 6 that is known in the art directs blood through the inner lumen 79 of the inner member 78 of the over-the-wire catheter. The blood flows through the inner lumen 79 and out of the catheter perfusion ports 5 to the tissue distal from the catheter 12.

As described above, the delivery sheath 10 provides a protective cover for the stent 16 while the stent is being transported through the vasculature of the patient. Once the damaged area has been crossed, the stent then is ready to be deployed.

10 In order to deploy the stent, a manipulator handle 70 is utilized to retract the delivery sheath 10. The proximal end (not shown) of the proximal retractable sheath 75 is attached to a connector 72. A sheath retraction switch 71 can be operated by the thumb of the physician by moving the switch in the proximal direction. The sheath retraction switch 71 is attached to the connector 72, which is slidably mounted in an elongated slot 73. As the sheath retraction switch 71 is moved in the proximal direction, the proximal retractable sheath 75 and the distal retractable sheath 74 also move in the proximal direction. Because the delivery sheath 10 is connected to the distal retractable sheath 74, it too moves in the proximal direction a sufficient distance to expose the expandable stent 16 and the balloon 14. It is preferred to position a radiopaque marker 67 near the distal end of the delivery sheath 10 so that the physician can determine when the sheath 10 has been withdrawn a sufficient distance so as not to interfere with the deployment of the stent 16.

20 Alternatively, the radiopaque marker can be positioned at the location 68 (FIG. 14) rather than at the location indicated by the radiopaque marker 67. When the radiopaque marker 68 is positioned on the distal retractable sheath 74, it has a lower profile than the radiopaque marker 67, thus allowing the delivery sheath 10 to cross an occluded area more easily.

In order to deploy the expandable stent 16, the balloon 14 is inflated with an inflation fluid through an inflation port 65. As shown in FIG. 17, an inflation fluid supply 7, known in the art, directs inflation fluid into the balloon 14. After the expandable stent 16 has been deployed, the balloon 14 is deflated and the intravascular catheter 12 is removed from the vasculature of the patient.

In the preferred embodiment of the present invention, the dimensions of the intravascular catheter generally follow the dimensions of intravascular catheters used in angioplasty procedures in the same arterial location. Typically, the length of a catheter for use in the coronary arteries is about 150 cm (59 inches), the outer diameter of the catheter shaft is about 0.89 mm (0.035 inch), the length of the balloon typically is about 2 cm (0.79 inch) and the inflated diameter about 1 mm to about 8 mm (0.04 to 0.31 inch).

The materials of construction may be selected from those used in conventional balloon angioplasty catheters, such as those described in the patents referenced hereinabove. The delivery sheath generally will be slightly shorter than the intravascular catheter, e.g., by about the length of the manipulating devices 15 or 50, with an inner diameter large enough to accommodate the intravascular catheter and to allow the catheter free longitudinal movement within the delivery sheath. The sheath and the catheter shaft can be made of conventional polyethylene tubing.

While the present invention has been described herein in terms of delivering an expandable stent to a desired location within a blood vessel of a patient, the delivery system can be employed to deliver stents to locations within other body lumens such as the urethra or the Fallopian tubes so that the stents can be expanded to maintain the patency of these body lumens. Various changes and improvements also may be made to the invention without departing from the scope thereof.

## 45 Claims

1. A catheter assembly for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of an expandable stent (16) within the body lumen, comprising:

50 an elongated sheath (10) having proximal and distal ends, a sheath lumen (11) extending therein, a first port (17) in the distal end being in fluid communication with the sheath lumen, and at least one sheath perfusion port (1, 2) in the sheath in fluid communication with the sheath lumen;

an elongated catheter (12) disposed within the sheath lumen (11) and having a proximal and a distal end wherein the catheter includes at least one catheter perfusion port (3), the elongated catheter having an outer member and an inner member, an expandable member (14) proximally adjacent to the distal end of the outer member that receives the expandable stent (16) on the exterior thereof, an inner lumen (22) within said inner member that receives a guiding member (26) therein and that extends the entire length of the inner lumen, the inner lumen also being in fluid communication with the catheter perfusion port (3); and



means (15, 33, 34) for adjusting the relative axial positions of the catheter (12) and the sheath (10) to expose the expandable member so that expansion thereof expands the expandable stent, and permits blood flows through the first port (1,2) in the sheath (10) and the at least one catheter perfusion port (3).

2. A system for the delivery of an expandable stent (16) within a body lumen over a guiding member (26) comprising:

an elongated sheath (10) having proximal and distal ends, a sheath lumen (11) extending therein, a first port (17) in the distal end of said sheath being in fluid communication with the sheath lumen (11), and a perfusion port (1, 2) in the sheath in fluid communication with the sheath lumen;

an elongated catheter (12) slidably disposed within the sheath lumen (11), an expandable member (14) proximally adjacent to the distal end of the catheter which receives on the exterior thereof the expandable stent (16), an inner lumen (22) extending the length of said elongated catheter for receiving the guiding member (26) therein and which extends the entire length of the inner lumen, and at least one catheter perfusion port (3) in the catheter in fluid communication with the inner lumen; and

means (15, 33, 34) for adjusting the relative axial positions of the catheter (12) and the sheath (10) to expose the expandable member (14) and the expandable stent (16).

3. The stent delivery system of claim 2, wherein the sheath (10) has a tapered portion on the distal end.

4. A catheter assembly for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of an expandable stent (16) within the body lumen, comprising:

an elongated sheath (10) having a proximal end and a distal end, a flared portion proximal to the distal end, a tapering portion proximal to the flared portion, a sheath lumen (11) extending therein, a first port (17) in the distal end and a second port at the proximal end (18), both of the ports (17, 18) being in fluid communication with the sheath lumen, and at least one sheath perfusion port (1,2) in the sheath in fluid communication with the sheath lumen;

an elongated catheter (12) slidably disposed within the sheath lumen (11), an expandable member (14) proximally adjacent to the distal end of the catheter which receives on the exterior thereof the expandable stent (16), an inner lumen (22) extending the length of said elongated catheter for receiving a guiding member (26) therein and which extends the entire length of the inner lumen, and at least one catheter perfusion port (3) in the catheter in fluid communication with the inner lumen (22);

an elastic cone (58) having a proximal end and a distal end and having a small aperture (61) in the distal end and a large aperture (60) in the proximal end thereof, the large aperture receiving the distal end of the elongated sheath (10); and

a manipulator handle (70) having a switch (71) adapted to move axially in the handle, the switch attached to the proximal end of the sheath so that as the switch is moved proximally the sheath moves proximally to expose the stent (16) and the expandable member (14).

5. The catheter as defined in claim 4, wherein the sheath perfusion port (1, 2) includes a plurality of vertical slots.

6. The catheter as defined in claim 4, wherein the sheath perfusion port (1, 2) includes a plurality of horizontal slots.

7. The catheter as defined in claim 4, wherein the catheter perfusion port (3) includes a plurality of slots.

8. The catheter as defined in claim 4, wherein the sheath further comprises a sheath perfusion port in fluid communication with the sheath lumen and being located at the distal end of the sheath.

9. A method of delivering an expandable stent to a desired location within a patient's body lumen which has a guide wire disposed therein with a proximal end extending out of the patient, the method comprising the steps of:

providing an elongated sheath with an sheath lumen therein and a sheath perfusion port in fluid communication with the sheath lumen, the sheath having proximal and distal ends, and a first port in the distal end of the sheath; providing an elongated catheter disposed within the elongated sheath, the catheter having an expandable member proximally adjacent to the distal end of the catheter and having mounted on the exterior thereof the expandable stent, the catheter having an inner lumen adapted to slidably receive a guide wire therein, the guide wire extending the entire length of the inner lumen, wherein the catheter further includes a catheter perfusion port in fluid communication with the inner lumen;

advancing the sheath and catheter over the guide wire through the body lumen to the desired location therein;  
adjusting the relative axial position of said sheath with respect to said catheter to expose the expandable stent  
on the expandable member;  
expanding the expandable member to expand the stent mounted thereon at the desired location within the  
body lumen;  
contracting the expandable member on the catheter; and  
withdrawing the catheter and sheath from the body lumen.

10. The method of claim 9, wherein the expandable member includes a balloon and wherein an inflation fluid is directed  
to the interior of the balloon to expand the balloon and thereby expand the stent mounted thereon.

11. The method of claim 9, wherein the method further comprises the step of perfusing a fluid through the sheath  
perfusion port.

12. The method of claim 9, wherein the step of providing an elongated sheath includes a sheath having a plurality of  
perfusion ports.

FIG. 1

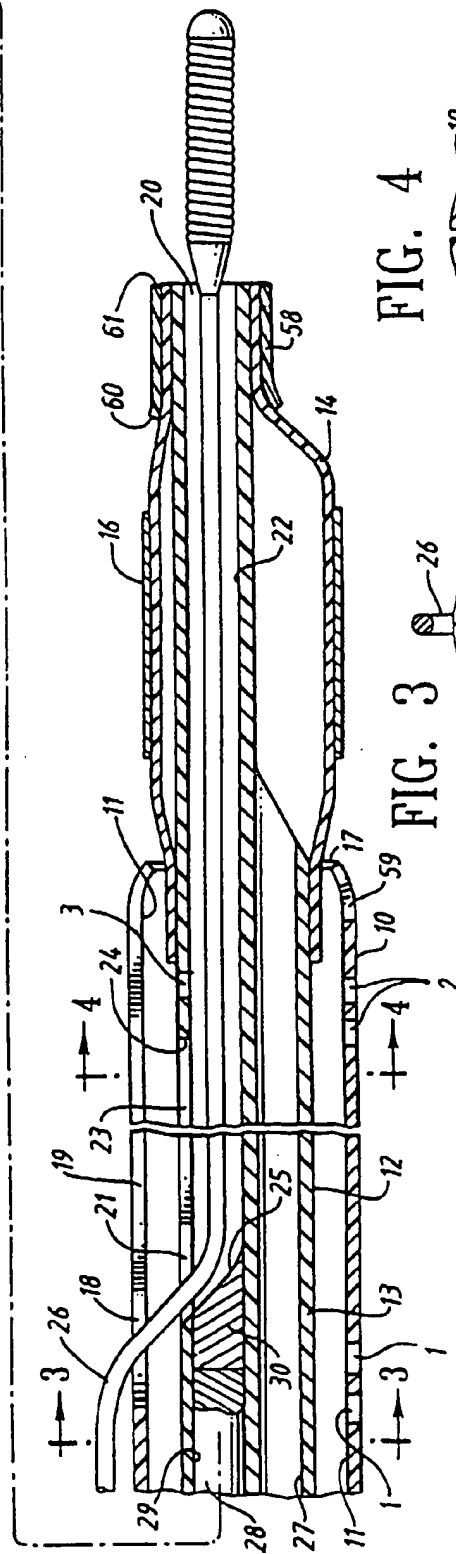
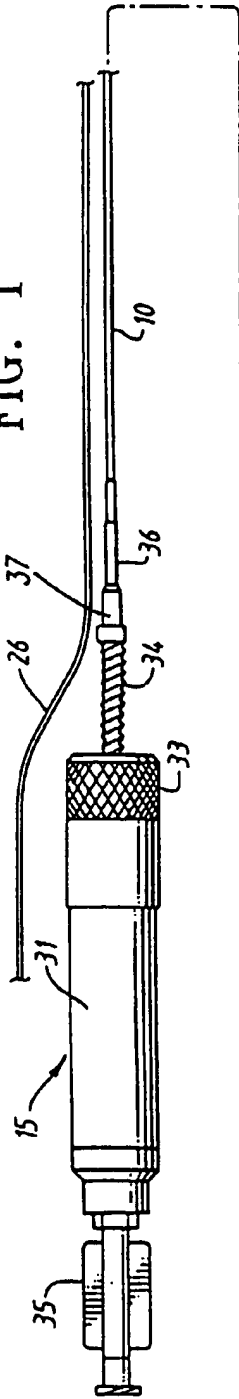


FIG. 4

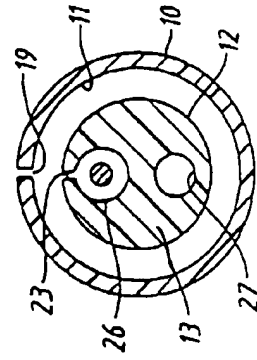


FIG. 3

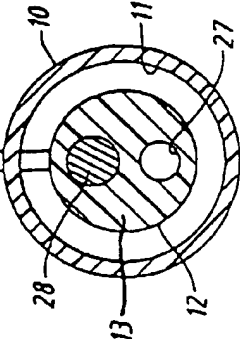


FIG. 2

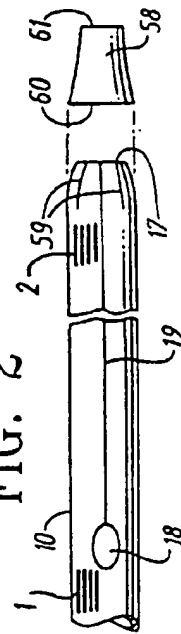


FIG. 5

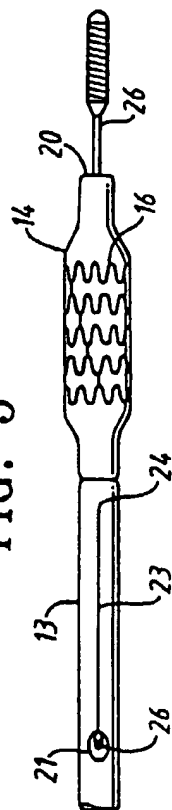


FIG. 6

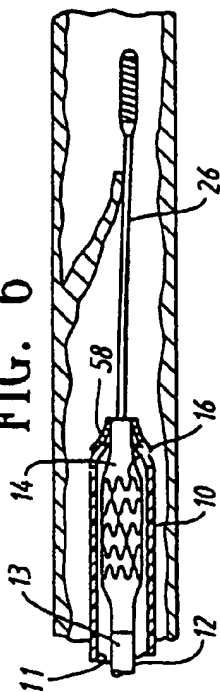


FIG. 7

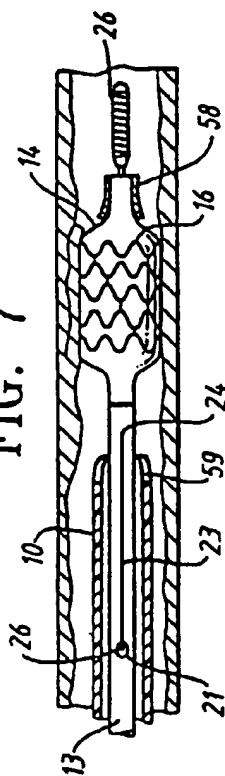


FIG. 8

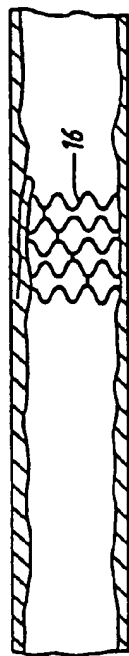
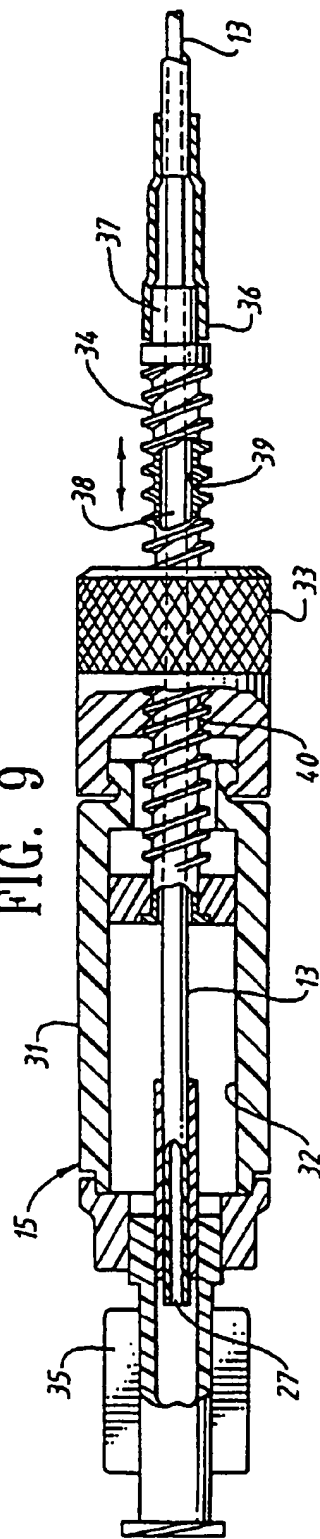
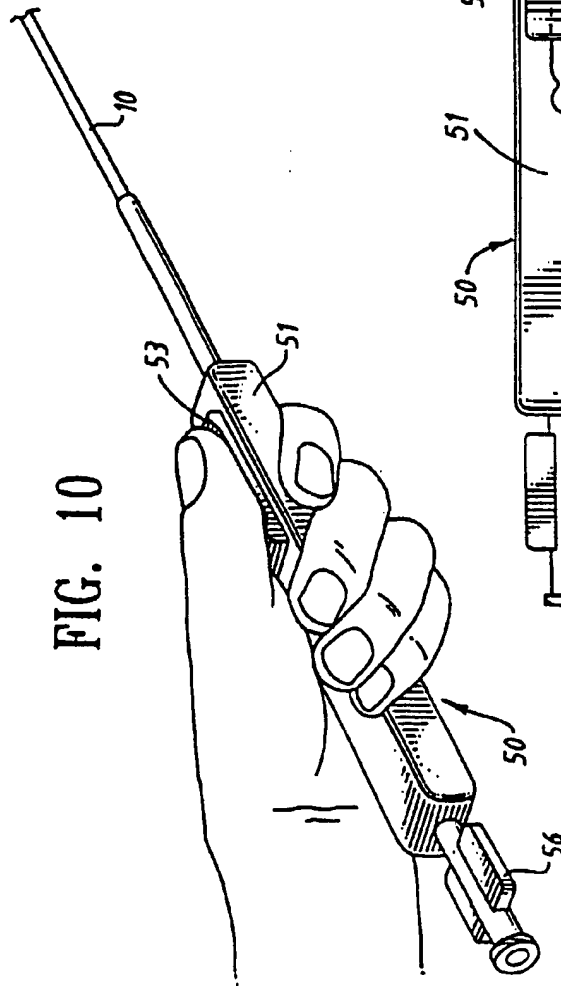
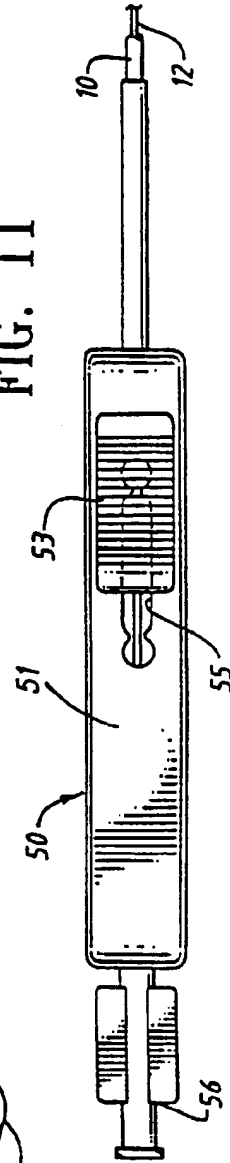


FIG. 9

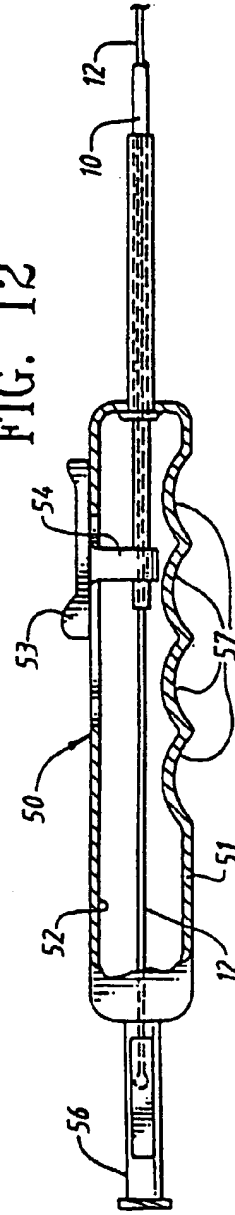




**FIG. 11**



**FIG. 12**



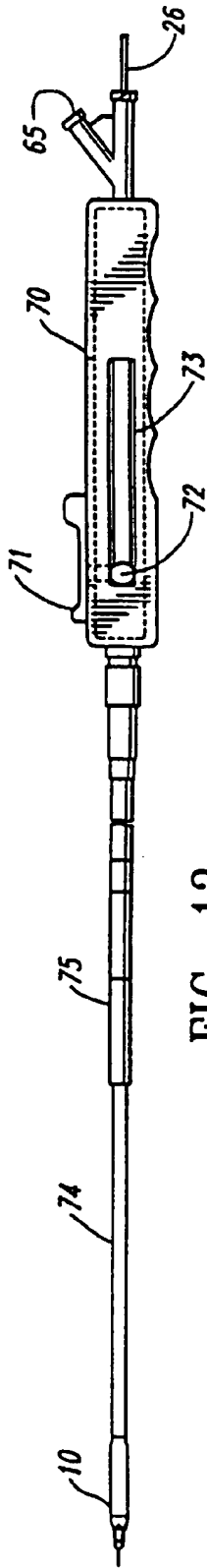


FIG. 13

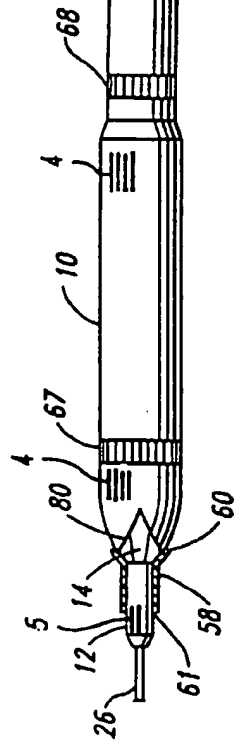


FIG. 14

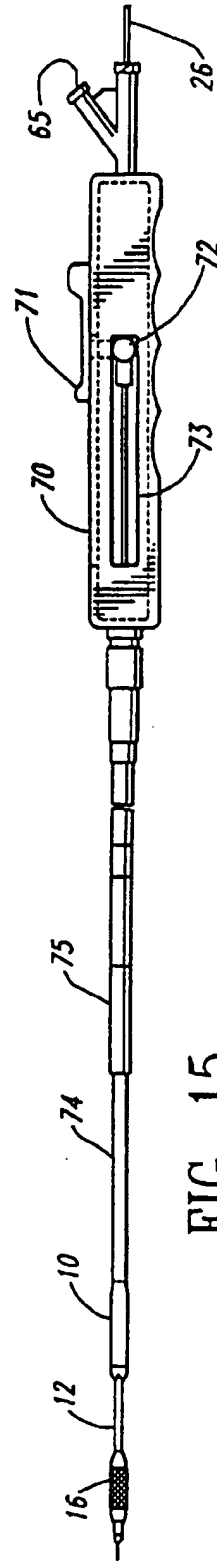


FIG. 15

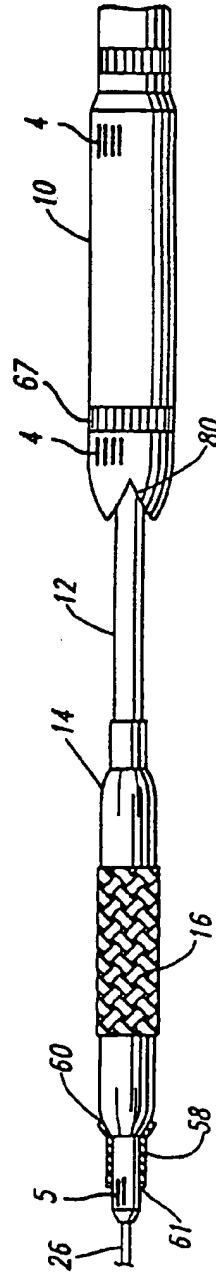
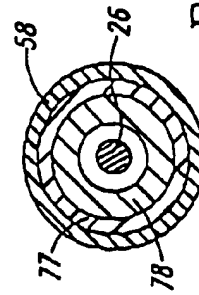
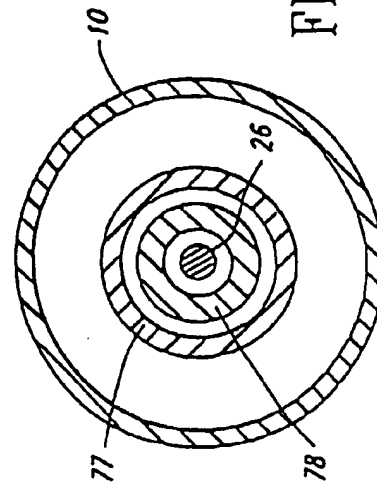
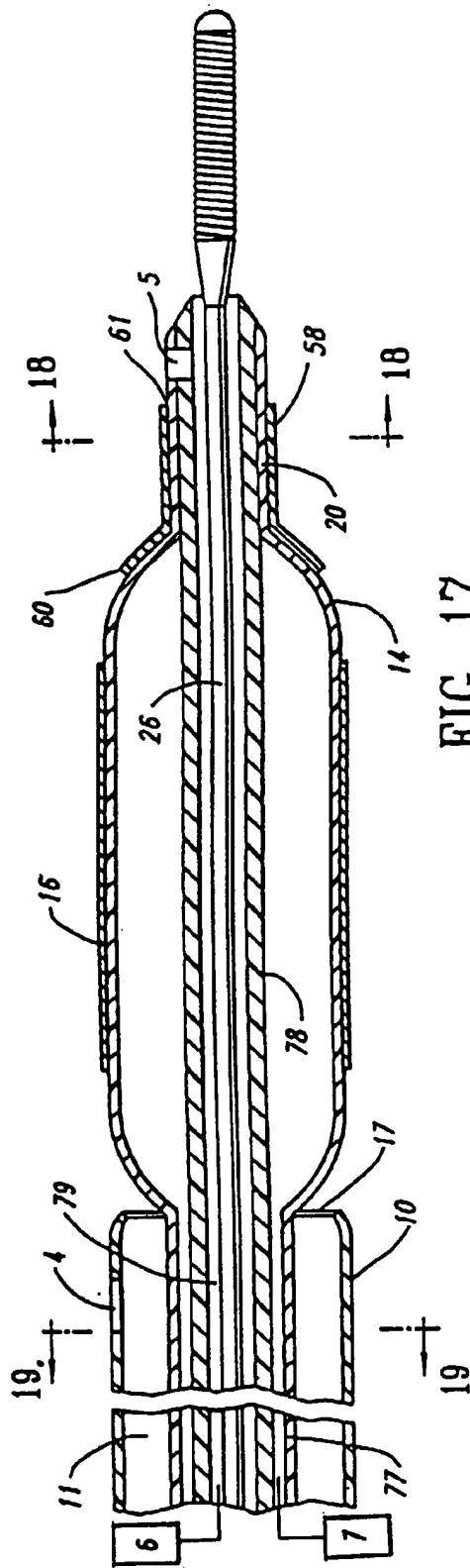


FIG. 16





European Patent  
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# PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 98 30 3534  
shall be considered, for the purposes of subsequent  
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP 0 505 686 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 30 September 1992 * abstract * * page 4, line 43 - page 5, line 16; figures 1-4 *	1-8	A61F2/06
A	EP 0 442 657 A (C.R. BARD, INC.) 21 August 1991 * column 6, line 46 - column 7, line 18; figures 4,7,8,13 *	4	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61F A61M
INCOMPLETE SEARCH			
<p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely : 1-8</p> <p>Claims searched incompletely : 9-12</p> <p>Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search		Date of completion of the search	Examiner
THE HAGUE		7 August 1998	Michels, N
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons</p>	
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p>		<p>&amp; : member of the same patent family, corresponding document</p>	

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